Title

A Medical Device

Field of the Invention

The present invention relates to a medical device for insertion into a bodily vessel to treat an aneurysm.

Background of the Invention

Vascular diseases include aneurysms causing hemorrhage, atherosclerosis causing the occlusion of blood vessels, vascular malformation and tumors. Vessel occlusion or rupture of an aneurysm within the brain causes of stroke. Aneurysms fed by intracranial arteries can grow within the brain to a point where their mass and size can cause a stroke or the symptoms of stroke, requiring surgery for removal of the aneurysms or other remedial intervention.

Occlusion of coronary arteries, for example, is a common cause of heart attack. Diseased and obstructed coronary arteries can restrict the flow of blood in the heart and cause tissue ischemia and necrosis. While the exact etiology of sclerotic cardiovascular disease is still in question, the treatment of narrowed coronary arteries is more defined. Surgical construction of coronary artery bypass grafts (CABG) is often the method of choice when there are several diseased segments in one or multiple arteries. Conventional open-heart surgery is, of course, very invasive and traumatic for patients undergoing such treatment. Therefore, alternative methods being less traumatic are highly desirable.

One of the alternative methods is balloon angioplasty that is a technique in which a folded balloon is inserted into a stenosis, which occludes or partially occludes an artery and is inflated to open the occluded artery. Another alternative method is atherectomy that is a technique in which occlusive atheromas are cut from the inner surface of the arteries. Both methods suffer from reocclusion with certain percentage of patients.

A recent preferred therapy for vascular occlusions is placement of an expandable metal wire-frame including a stent, within the occluded region of blood vessel to hold it open. The stent is delivered to the desired location within a vascular system

by a delivery means, usually a catheter. Advantages of the stent placement method over conventional vascular surgery include obviating the need for surgically exposing, removing, replacing, or by-passing the defective blood vessel, including heart-lung by-pass, opening the chest, and general anaesthesia.

When inserted and deployed in a vessel, duct or tract ("vessel") of the body, for example, a coronary artery after dilatation of the artery by balloon angioplasty, a stent acts as a prosthesis to maintain the vessel open. The stent usually has an open-ended tubular form with interconnected struts as its sidewall to enable its expansion from a first outside diameter which is sufficiently small to allow the stent to traverse the vessel to reach a site where it is to be deployed, to a second outside diameter sufficiently large to engage the inner lining of the vessel for retention at the site. A stent is typically delivered in an unexpanded state to a desired location in a body lumen and then expanded. The stent is expanded via the use of a mechanical device such as a balloon, or the stent is self-expanding.

Usually a suitable stent for successful interventional placement should possess features of relatively non-allergenic reaction, good radiopacity, freedom from distortion on magnetic resonance imaging (MRI), flexibility with suitable elasticity to be plastically deformable, strong resistance to vessel recoil, sufficient thinness to minimize obstruction to flow of blood (or other fluid or material in vessels other than the cardiovascular system), and biocompatibility to avoid of vessel re-occlusion. Selection of the material of which a stent is composed, as well as design of the stent, plays an important role in influencing these features.

Furthermore, implantable medical devices have been utilized for delivery of drugs or bioreagents for different biological applications. Typically, the drugs or bioreagents are coated onto the surfaces of the implantable medical devices or mixed within polymeric materials that are coated onto the surfaces of the implantable medical devices. However, all the current available methods suffer from one or more problems including uncontrollable release, form limitations of drugs, and bulky appearance.

Therefore, there is desire for an implantable medical device that is able to deliver drugs or reagents efficiently to the endovascular system, especially intracranial blood vessels.

Summary of the Invention

In a first preferred aspect, there is provided a medical device for insertion into a bodily vessel to treat an aneurysm, the device comprising:

a mechanically expandable device expandable from a first position to a second position, said mechanically expandable device is expanded radially outwardly to the second position such that the exterior surface of said mechanically expandable engages with the inner surface of the vessel so as to maintain a fluid pathway through said vessel; and

a membrane expandable from a first position to a second position in response to expansion of said mechanically expandable device, said membrane obstructing blood circulation to the aneurysm when expanded to the second position, and at least a portion of the membrane is secured to the mechanically expandable device to maintain the position of the membrane relative to the mechanically expandable device when expanded to the second position.

The mechanically expandable device may comprise a generally tubular structure having an exterior surface defined by a plurality of interconnected struts having interstitial spaces therebetween.

The membrane may be made of a biocompatible and elastomeric polymer.
The membrane may have a thickness of about 0.001 to 0.005" with pore or hole sizes of about 20 to 100 microns.
The membrane may be made from polymeric material or biodegradable material.
The biodegradable material may form multiple sub-layers mixed with drugs or reagents.

The membrane may be capable of isotropic expansion. The membrane may expand from a deliverable shape when crimped on a delivery system to a deployed shape. Thus, the initial size of membrane (as fabricated by attaching to the stent struts) may be equivalent to a diameter of 1.5 to 2.5mm. After that, the membrane may experience shrinkage during crimping (together with the mechanically expandable device) onto delivery catheter. The mechanically expandable device with the membrane may have diameter equal to 0.5 to 0.9mm. After deployment, the membrane may reach a diameter up to 2.5 to 4.5mm. A suitable material for membrane fabrication may be an elastomeric polymer which is able be elongated up to 600 to 800%. For example, modified polyurethanes or silicon.

The membrane may be disposed on the exterior surface of the device.
The membrane may completely surround the device.
The membrane may circumferentially surround a portion of the device.
The membrane may cover a portion of the device.

The membrane may be non-porous and non-permeable to prevent blood circulation to the aneurysm. The membrane may be made from a solid polymer.

The membrane may be permeable and porous. The membrane may have holes or pores such that blood supply to perforations and microscopic branches of main brain arteries is permitted but blood supply to the aneurysm is prevented. The membrane may have pores between 20 to 100 microns in size. The membrane may have fabricated holes between 20 to 100 microns in size. The holes may be fabricated by laser drilling. The distance between the pores or holes may be less than 100µm.

Advantageously, a permeable membrane is ideal in some parts of cerebral arteries with microscopic branches named perforations. It is important not to block these perforations while placing the membrane against the aneurysm. This blocks accessibility to the areas of the brain where blood supply is provided by the perforations. On the other hand, a permeable membrane obstructs blood circulation into aneurysm.

The membrane may comprise a plurality of polymeric strips secured to the mechanically expandable device. The strips may be less than 0.075mm and the distance between adjacent strips is less than 100µm.

The membrane may comprise a mesh secured to the mechanically expandable device. The spaces of the mesh may be less than 100µm and the width of the meshing may be between 0.025 to 0.050mm.

The aneurysm may be a regular size, giant or wide neck aneurysm.

The mechanically expandable device may be self-expandable or balloon expandable.
The mechanically expandable device may be a stent.

The membrane may be supported by the generally tubular structure and is attached to at least one strut.

The membrane may be a tubular structure having a diameter similar to a nominal initial diameter of the stent; and wherein the membrane is disposed onto the outer surface of the stent or introduced by dip coating or spraying or any other suitable manufacturing method between the struts of the stent. In this case, the struts may be encased by a polymer used to make the membrane.

The membrane may be a segment of a tubular structure disposed onto a portion of the outer surface of the stent.

The at least one reagent may be in any one form selected from the group consisting of: solid tablet, liquid and powder.

At least one radiopaque marker may be provided on the mechanically expandable device to improve visibility of the device during and after insertion. The at least one radiopaque marker may be made from gold or platinum. Center radiopaque markers and end radiopaque markers may be provided on the mechanically expandable device.

In a second aspect, there is provided a medical device for treating a bifurcation or trifurcation aneurysm between at least two bodily vessels, the device comprising:

a first mechanically expandable device for inserting into a first vessel;

a second mechanically expandable device for inserting into a second vessel;

each mechanically expandable device expandable from a first position to a second position, said mechanically expandable device is expanded radially outwardly to the second position such that the exterior surface of said mechanically expandable device engages with the inner surface of the vessel so as to maintain a fluid pathway through said vessel; and

a membrane expandable from a first position to a second position in response to expansion of said mechanically expandable devices, said membrane obstructing blood circulation to the aneurysm when expanded to the second position, and at least a portion of the membrane is secured to each mechanically

expandable device to maintain the position of the membrane relative to the mechanically expandable devices when expanded to the second position.

In a third aspect, there is provided a method of making a medical device as described, the method comprising:

disposing the generally tubular structure on a mandrel; and

disposing the membrane onto the outer surface of the mechanically expandable device.

In a fourth aspect, there is provided a method of making a medical device as described, the method comprising:

disposing the generally tubular structure on a mandrel; and

incorporating the membrane between the struts of the stent.

The disposing may be any one selected from the group consisting of: spraying, suture, lamination, adhesion, heat and dip coating.

One object of at least one embodiment of the present invention is to mechanically seal or obstruct blood circulation to an aneurysm, causing the aneurysm to eventually dry out.

Brief Description of the Drawings

An example of the invention will now be described with reference to the accompanying drawings, in which:

Figures 1A and 1B are two exemplary balloon expandable stents;

Figure 2 shows a self-expanding stent;

Figure 3A is diagrammatic view of a stent disposed in the location of an aneurysm;

Figure 3B is diagrammatic view as Figure 3A except that a port of the stent is formed of opened cells;

Figure 4 shows a delivery system with a stent expanded onto the balloon;

Figure 5 is diagrammatic view of a stent partially covered by a membrane with pockets;

Figure 6 is a cross-sectional view of a sleeve as a membrane supported by two ring-like stents;

Figure 7 is a diagrammatic view of a membrane joining two stents for treating a bifurcation aneurysm;

Figure 8 is a diagrammatic view of an aneurysm covered with the membrane of a stent to obstruct blood circulation to the aneurysm;
Figure 9 is a table of typical dimensions for the stent;
Figure 10 is a diagrammatic view of a stent with a membrane having a pattern of pores;
Figure 11 is a diagrammatic view of a stent with a membrane having polymer strips;
Figure 12 is a diagrammatic view of a stent with a membrane having a mesh'
Figure 13 is a diagrammatic view of a membrane secured to the struts of a stent;
Figure 14 is a diagrammatic view of a membrane before the stent is deployed;
Figure 15 is a diagrammatic view of a stent with a membrane secured at three different positions and with three different sizes; and
Figure 16 is a diagrammatic view of a membrane flipping inside the vessel rather than staying close the vessel wall.

Detailed Description of the Drawings

Implantable medical devices include physical structures for delivering drugs or reagents to desired sites within the endovascular system of a human body. Implantable medical devices may take up diversified shapes and configurations depending upon specific applications. Common implantable medical devices include stents, vena cava filters, grafts and aneurysm coils. While stents are described, it is noted that the disclosed structures and methods are applicable to all the other implantable medical devices.

The endovascular system of a human body includes blood vessels, cerebral circulation system, tracheo-bronchial system, the biliary hepatic system, the esophageal bowel system, and the urinary tract system. Although exemplary stents implantable 202 in blood vessels are described, they are applicable to the remaining endovascular system.

Stents 202 are expandable prostheses employed to maintain vascular and endoluminal ducts or tracts of the human body open and unoccluded, such as a portion of the lumen of a coronary artery after dilatation of the artery by balloon angioplasty. A typical stent 202 is a generally tubular structure having an exterior surface defined by a plurality of interconnected struts having interstitial spaces there between. The generally tubular structure is expandable from a first position,

wherein the stent is sized for intravascular insertion, to a second position, wherein at least a portion of the exterior surface of the stent contacts the vessel wall. The expanding of the stent is accommodated by flexing and bending of the interconnected struts throughout the generally tubular structure. It is contemplated that many different stent designs can be produced. A myriad of strut patterns are known for achieving various design goals such as enhancing strength, maximizing the expansion ratio or coverage area, enhancing longitudinal flexibility or longitudinal stability upon expansion, etc. One pattern may be selected over another in an effort to optimize those parameters that are of particular importance for a particular application.

Referring to Figures 1A and 1B, there are provided two exemplary balloon expandable stent designs. Figure 1A shows a tubular balloon expandable stent 100 with end markers 103 to increase visibility of the stent 100. The stent 100 is composed of stent struts of a ring 101, ring connectors 102, and end markers 103.

Referring to Figure 1A, the stents 100 are made of multiple circumstantial rings 101, where the ring connectors 102 connect two or three adjacent rings 101 to hold the rings in place. For the end markers 103, Figure 1A shows a "disc" shaped marker. Actually, the shape is not critical so long that the marker can be used to increase further visibility to the stents 100. Figure 1B shows a tubular balloon expandable stent 104 which is similar to the stent 100 as shown in Figure 1A except that the stent 104 comprises of center markers 105, 106. The center markers 105, 106 help to locate an aneurysm opening during an implantation operation. The center markers 105, 106 can be of the same material and shape as the end markers 103.

Referring to Figure 2, there is provided a self-expanding stent 107 that is made of wires/ribbons. While a self-expanding stent may have many designs, Figure 2 shows the stent 107 having a typical braided pattern 108 with welded ends 109. The stent 107 is so designed that is relatively flexible along its longitudinal axis to facilitate delivery through tortuous body lumens, but that is stiff and stable enough radially in an expanded condition to maintain the patency of a body lumen, such as an artery when implanted therein.

Turning to Figure 4, it is shown an expanded tubular stent 112. When the tubular stent 112 is fully expanded to its deployed diameter, the latticework of struts takes

on a shape in which adjacent crests undergo wide separation, and portions of the struts take on a transverse, almost fully lateral orientation relative to the longitudinal axis of the stent. Such lateral orientation of a plurality of the struts enables each fully opened cell to contribute to the firm mechanical support offered by the stent in its fully deployed condition, to assure a rigid structure which is highly resistant to recoil of the vessel wall following stent deployment.

While a stent 112 may be deployed by radial expansion under outwardly directed radial pressure exerted, for example, by active inflation of a balloon of a balloon catheter on which the stent is mounted, the stent 112 may be self-expandable. In some instances, passive spring characteristics of a preformed elastic (i.e., self-opening) stent serve the purpose. The stent is thus expanded to engage the inner lining or inwardly facing surface of the vessel wall with sufficient resilience to allow some contraction but also with sufficient stiffness to largely resist the natural recoil of the vessel wall.

In one embodiment, the implantable medical devices are intracranial stents 202 and delivery systems for stenotic lesions and aneurysms 201. Due to the characteristics of intracranial blood vessels, the intracranial stents 202 are designed to be very flexible, low profile (0.033" – 0.034" or even less as crimped onto delivery catheter) and thin wall (0.0027"- 0.0028"). The intracranial stents 202 do not necessarily have the highest possible radial strength because there is no need of high strength for intracranial applications. The radiopacity of the intracranial stents may be provided by either including radiopaque markers 205 made from gold or platinum or making the stents 202 from platinum/iridium/tungsten alloys. Stents 202 for treating aneurysms 201 have a special type of platinum "star markers" 204 in the middle of their bodies to assist in precise indication and alignment of the stents 202 over the aneurysm neck 201 and allow further operation with aneurysms 201.

As shown in Figure 3A, the intracranial stent 202 is disposed in the location of an aneurysm 201. The membrane 203 partially covers the stent 202 and is positioned to seal the neck of the aneurysm 201. The radiopaque markers 204 are located in the middle of the stent 202 to provide visibility of the stent 202 during operation and post-operation inspection. Referring to Figure 3B, a portion of the stent 202 is formed of opened cells 205. This design avoids blocking perforations. The perforations refer to small capillary vessels that have important and distinctive

blood supply functions. It is possible that tubular stents can block perforations and inhibit important functions.

Referring to Figure 4, the delivery system includes a guide wire lumen 110, a balloon inflating lumen 111, a connector 116, a balloon catheter shaft 113, and platinum marker bands 115 on the catheter shaft 113. The guide wire lumen 110 is used for introducing a guide wire in a balloon catheter, and the balloon inflating lumen 111 for inflating the balloon after the stent to be placed reaches its targeted location. The connector 116 is used for separating the guide wire lumen 110 and the balloon inflating lumen 111. The balloon catheter shaft 113 carries the guide wire lumen 110 and the balloon inflating lumen 111 separately, with a typical length of about 135-170 cm. The ring markers 115 on the catheter shaft 113 are used for showing the start of balloon tapers and the edges of the stent. In Figure 3, an expanded stent 112 is shown being mounted onto an expanded balloon. The delivery catheter can be essentially a conventional balloon dilatation catheter used for angioplasty procedures. The balloon may be formed of suitable materials such as irradiated polyethylene, polyethylene terephthalate, polyvinylchloride, nylon, and copolymer nylons such as Pebax™. Other polymers may also be used. In order for the stent to remain in place on the balloon during delivery to the desired site within an artery, the stent is crimped onto the balloon.

In a preferred embodiment, the delivery of the stent is accomplished in the following manner. The stent is first mounted onto the inflatable balloon on the distal extremity of the delivery catheter. Stent is mechanically crimped onto the exterior of the folded balloon. The catheter/stent assembly is introduced within vasculature through a guiding catheter. A guide wire is disposed across the diseased arterial section and then the catheter/stent assembly is advanced over a guide wire within the artery until the stent is directly under the diseased lining. The balloon of the catheter is expanded, expanding the stent against the artery. The expanded stent serves to hold open the artery after the catheter is withdrawn. Due to the formation of the stent from an elongated tube, the undulating component of the cylindrical elements of the stent is relatively flat in transverse cross-section, so that when the stent is expanded, the cylindrical elements are pressed into the wall of the artery and as a result do not interfere with the blood flow through the artery. The cylindrical elements of the stent which are pressed into the wall of the artery will eventually be covered with endothelial cell layer which further minimizes blood flow interference. Furthermore, the closely spaced cylindrical elements at regular

intervals provide uniform support for the wall of the artery, and consequently are well adopted to tack up and hold in place small flaps or dissections in the wall of the artery.

For resilient or self-expanding prostheses, they can be deployed without dilation balloons. Self-expanding stents can be pre-selected according to the diameter of the blood vessel or other intended fixation site. While their deployment requires skill in stent positioning, such deployment does not require the additional skill of carefully dilating the balloon to plastically expand the prosthesis to the appropriate diameter. Further, the self-expanding stent remains at least slightly elastically compressed after fixation, and thus has a restoring force which facilitates acute fixation. By contrast, a plastically expanded stent must rely on the restoring force of deformed tissue, or on hooks, barbs, or other independent fixation elements.

The presence of a stent in a vessel tends to promote thrombus formation as blood flows through the vessel, which results in an acute blockage. In addition, as the outward facing surface of the stent in contact or engagement with the inner lining of the vessel, tissue irritation can exacerbate restenosis attributable to hyperplasia. Moreover, it is desirable to deliver drugs or reagents into the aneurysms to enhance the blockage of blood flow into the aneurysms. Finally, implantable medical devices have been used as vehicles to deliver drugs or reagents to specific locations within the vascular system of a human body.

In one example, an intracranial stent 202 is specially designed for low pressure deployment. The stent 202 has adequate radial strength for targeting a specific environment of fragile intracranial vessel. The stent 202 is designed to allow for delivering high stent performance and absolutely conforming longitudinal flexibility.

Low pressure deployment of a stent is defined as a pressure equal to or below 4atm. This level of pressure enables the stent 202 to be fully deployed to support a stenosed intracranial vessel or aneurysm neck 201 without introducing trauma or rapture of a target vessel. The stent 202 can be deployed using balloon techniques or be self-expandable.

The stent 202 comprises structural elements that restrict potential over expansion, matching the inner diameter of the vessel and to make deployment extremely

precise. This feature of the structural elements in combination with low pressure deployment potentially reduces vessel injury, rupture or restenosis.

The stent 202 also has longitudinal flexibility equal to or better than what is provided by a delivery catheter. This means that the stent does not add increased rigidity to the device. The trackability of the stent 202 depends on the mechanical properties of the catheter and is not restricted by stent 202 alone. The longitudinal flexibility of the stent 202 can be measured by force in grams to deflect the stent from neutral line. This force brings stent deflection to 1mm for less than 8 grams. Existing catheters can provide 20-22 grams per 1mm deflection. This condition is also extremely important when creating stent compliance to particular vessels and saves the vessel from possible traumatic reaction.

The structure of the stent 202 is designed to provide a normalized radial force of 18-19grams/mm of length and may reach values close to the ones found in existing coronary stents. Stent structural support provides 3-4% of deflection of the stent structure together with intracranial vessel wall natural pulsing. This leads to greater stent conformity and a reduced vessel injury score.

- The intracranial stent 202 has profile in compressed delivery mode .020"
- The intracranial stent 202 is designed to be compressed onto delivery catheter with a profile as low .014"-.016" having stent profile .020"-.022".
- The intracranial stent 202 has even material distribution and wall coverage, creating needed vessel support. The material ratio is in the range of 10-17% depending on deployment diameter.
- The intracranial stent 202 has a strut thickness and width not larger than .0028". Strut dimensions are selected which make the least intrusive stent material volume and to reduce the vessel injury score.

The stent surface to length ratio is set to be 1.1-1.3mm²/mm to provide minimal vessel injury score.

At least one membrane 203 is disposed onto the outer surface of a stent 202. The membrane 203 comprises pockets which serve as receptacles for drugs or reagents to deliver the drugs or reagents into vascular systems. The membrane 203 covers a part of a stent 202 as shown in Figures 3A and 3B, wherein the size of the membrane 203 is variable depending on application. In one example, the

membrane 203 covers the whole outer surface of a stent 202. Thus, the membrane 203 may be in any shape or size.

In certain embodiments, the membrane 203 comprises a first layer attached to the outer surface of an implantable medical device such as a stent 202. An intermediate layer is attached to the first layer wherein the intermediate layer comprises at least two circumferential strips being separated from each other and a second layer covering the first layer and the intermediate layer. The spaces surrounded by the first layer, the circumferential strips and the second layer form the pockets that serve as receptacles for drugs or reagents. In other embodiments, the intermediate layer includes at least one opening so that the pockets can be formed within the openings. The shapes and sizes of the openings may vary in accordance with specific applications. As shown in Figure 5, a stent 202 is partially covered by a membrane 203 that comprises a first layer 206 and a second layer 207. Figure 5 also shows the drug releasing pores 208.

Many polymeric materials are suitable for making the layers of the membrane 203. Typically, one first layer is disposed onto the outer surface of a stent. The first layer has a thickness of 0.002" – 0.005" with pore sizes of 20 –30 microns and similar to nominal initial diameter.

In certain embodiments, the first layer serves as an independent membrane 203 to mechanically cover and seal aneurysms 201. In certain embodiments, the first and/or second layers can be comprised of biodegradable material as a drug or reagent carrier for sustained release.

It is desirable that the intermediate layer be formed of a material which can fuse to the first and second layers or attached to the first layer in a different manner. In certain embodiments, the intermediate layer may be merged with the first layer to form a single layer with recessions within the outer surface of the merged layer

The second and intermediate layers can be made of biodegradable material that contains drugs or reagents for immediate or sustained controlled release. After biodegradable material is gone through the degradation process, the membrane 203 is still in tact providing vessel support.

The second layer may be composed of a polymeric material. In preferred embodiments, the second layer has a preferable thickness of about 0.001" with pore sizes of about 70 – 100 microns.

The polymeric layers may also be formed from a material selected from the group consisting of fluoropolymers, polyimides, silicones, polyurethanes, polyurethanes ethers, polyurethane esters, polyurethaneureas and mixtures and copolymers thereof. Biodegradable polymeric materials can also be used.

The fusible polymeric layers may be bonded by adhering, laminating, or suturing. The fusion of the polymeric layers may be achieved by various techniques such as heat-sealing, solvent bonding, adhesive bonding or use of coatings.

Types of drugs or reagents that may prove beneficial include substances that reduce the thrombogenic, inflammatory or smooth muscle cell proliferative response of the vessel to the implantable medical devices. For example, cell inhibitors can be delivered in order to inhibit smooth muscle cells proliferation. In intracranial or some other applications fibrin sealants can be used and delivered to seal aneurysm neck and provide fibroblasts and endothelial cells growth. Specific examples of drugs or reagents may include heparin, phosporylcholine, albumin, dexamethasone, paclitaxel and vascular endothelial growth factor (VEGF).

The drug or reagents can be incorporated into the implantable medical devices in various ways. For example the drug or reagent can be injected in the form of a gel, liquid or powder into receptacles of the pockets. Alternatively the drug or reagent can be supplied in a powder which has been formed into a solid tablet positioned in the receptacles.

Another prerequisite of a successful treatment of these extremely small diameter vessels is that the stent delivery system is highly flexible to allow it to be advanced along the anatomy of the cerebral circulation. In addition, the total stent delivery system must be of extremely small profile, to treat diseased intra-cranial arteries generally ranging from 1.5mm to 5mm.

Referring to Figure 6, in certain embodiments a membrane 203 is embodied as a sleeve 301 supported by two ring-like short stents 302 at both ends of a device so that the membrane 203 covers the whole area of the device 302. There is no

scaffold support in the middle of the device 302. Radiopaque markers 303 are located at both ends of the stent 302. Depending on applications, the rings are balloon expandable and made from stainless steel or self-expandable made from NiTi (memory shaped nickel- titanium alloy).

The membrane 203 is part of a hemorrhagic stent structure designed to effectively occlude aneurysm neck and "recanalize" the vessel. It'll allow rebuilding vessel and essentially eliminating aneurysm. No need of expensive (and extra-traumatic, sometimes too massive) coiling is expected.

This device is a preferable solution to treat: giant and wide neck aneurysms, bifurcation and trifurcation aneurysms. It is also a preferred treatment solution for cc fistula ruptured in cavernous sinus, pseudoaneurysms, saccular aneurysms.

The membrane 203 is elastic to allow its own expansion five to six times without disintegration and detachment from the stent structure. The thickness of the membrane 203 is expected to be not more than .002" in crimped position and .001" in expanded form. The mechanical properties do not introduce extra rigidity to the intracranial stent 202 and have no resistance to stent expansion. The membrane material also allows an expanded membrane 203 to endure normal blood pressure.

The membrane 203 may be made from a solid polymer. Alternatively, the membrane 203 is not be solid, but is formed as strips between stent struts, or with a series of holes or ovals. The membrane 203 therefore could be porous, or woven mesh. The membrane 203 could also be designed and structured in a way such that there is a system of holes to allow blood penetration into the system of perforations and not allow it into the aneurysm 201.

For upper brain arteries above Siphon, a porous and permeable membrane 203 is ideal. Such a membrane 203 treat an aneurysm neck 201 without blocking microvessels (perforators). It is expected that interventional neuroradiologists (INRs) to be more willing to use the membrane 203 than other known techniques for dealing with aneurysm necks 201. The permeable membrane 203 has a system of holes or pores with borders between them not larger than 100 microns. The holes or pores may range between 50 to 100microns. The membrane 203 is able to significantly improve hemodynamics around the aneurysm 201, since it has a lower delivery profile and is more flexible compared to a stent 202 with a solid membrane 203.

For aneurysms 201 that occur below the ophthalmic artery, the membrane 203 is preferably made from a solid polymer because there is a reduced risk of undesirable blockage of perforators.

The membrane 203 is attached to the stent struts. The membrane 203 may be attached using spraying, a dipping technique or heat bonding to the intermediate polymeric layer. The stent 202 is placed on a mandrel (hard PTFE or metal), or hung on a hook and the PU solution is sprayed and solidified with a quick drying process. Alternatively, the stent 202 is placed on the mandrel or on the hook and submerged into a PU solution.

A biodegradable membrane 203 enables drug delivery and is later dissolved. There are applications where there is no need for a membrane 203 to exist after exceeding 15 to 20 days after placement and thus the membrane 203 could be dissolved.

The membrane 203 may be made from PU, Silicon, or any other elastomeric medical grade polymer.

Referring to Figure 7, a membrane 203 for bifurcational stents 202 to treat a bifurcation or trifurcation aneurysm 201 is provided. At least 30 to 35% of aneurysms are located at bifurcation sites of intracranial vessels. This membrane 203 is one-sided and non-circumferential. The bifurcation stents 202 are joined by a membrane 203 to cover the aneurysm ~~neck~~ 201. The same pattern can be applicable to self-expandable (super-elastic) or balloon expandable (stainless steel, CoCr, PtIr alloys) stents 202.

Referring to Figure 8, an aneurysm 201 is covered with the membrane 203 of an intracranial stent 202 to treat and prevent ischemic and hemorrhagic stroke. The intracranial stent 202 coupled with a membrane 203 acts as a scaffold to open clogged arteries, and as a cover to prevent blood circulation to the aneurysm 201.

Obstructing blood supply to the aneurysm 201 isolates the aneurysm 201 from normal blood circulation, and thereby eventually causes it to dry out. Complete obstruction to the aneurysm 201 may not be necessary.

Figure 9 provides a table with typical dimensions for the intracranial stent 202 for use with the membrane 203. The material for the membrane 203 is biocompatible, has good adhesion to stent struts made from stainless steel 316L, and is formed by a stable film. In other embodiments, the film is blood "permeable" rather than being a solid film. The covered sections, that is, the borders between pores or holes do not exceed 75µm so as to prevent any part of the stent 202 or the membrane 203 from blocking perforators. Several options can be undertaken to achieve this. The membrane 203 is made from a thin film that does not exceed 0.001" in width. The film has good expandability, and can expand up to 400% at a low force. The membrane 203 also has a shelf life or chemical stability at ambient conditions and is stable in sterilization conditions (Eto).

In one example, polyurethane is used to make the membrane 203. Specifically, solution grade aromatic, polycarbonate based polyurethane is used. The physical properties are: durometer (Shore)is 75A, tensile strength is 7500 psi and elongation to 500%.

Referring to Figure 10, to make a permeable membrane 203, holes are drilled into a solid film to form pores. The pore size is between 0.025 to 0.050mm, while the distance between pores is less than 100µm.

Referring to Figure 11, threading strips 203 of a polymer are wrapped laterally around the stent 202. The strips are interlaced above and below the struts of the stent. The width of the strips is less than 0.075mm and distance between adjacent strips is less than 100µm.

Referring to Figure 12, a sheet of weaved material 203 is wrapped around the stent 202. The mesh size of the sheet is around 0.025-0.050mm, while the width of the polymer is less than 100µm.

Referring to Figure 13, the film 203 completely surrounds the stent strut and is a stable solid film between the struts of the stent. The film between struts is either within the struts or on the outer struts. The polymeric film stays as close to vessel

wall as possible. This is to minimize the film "flipping" inside of vessel as shown in Figure 16.

Referring to Figure 14, the membrane 203 is secured onto the struts, and is difficult to dislodge or be torn from the stent 202. The thickness of the membrane 203 does not add any significant profile to the crimped assembly, that is, it contributes to less than 0.001" of the crimped stent profile. The membrane 203 also has uniform shrinkability.

Referring to Figure 15, the membrane 203 may completely cover the stent 202, cover the mid-section of the stent 202, or cover a radial section of the stent 202. The membrane 203 expands with the stent 202 and does not restrict or alter the expansion characteristics of the stent 202. The membrane 203 is easily expandable up to 400%. The membrane 203 has a minimum effect on the mechanical properties of the stent 202 such as flexibility, trackability, expandability, recoil and shortening. The membrane 203 is also stable in normal shelf life conditions and stable in sterilization conditions (Eto). The properties of the polymer film are preserved and not changed after sterilization. The membrane 203 is prevented from sticking to the balloon material (Nylon) after crimping. The membrane 203 is able to tolerate temperature variations (of up to 60C). The edges of the membrane 203 are aesthetically acceptable, and have smooth, not rough edges.

It will be appreciated by persons skilled in the art that numerous variations and/or modifications may be made to the invention as shown in the specific embodiments without departing from the scope or spirit of the invention as broadly described. The present embodiments are, therefore, to be considered in all respects illustrative and not restrictive.